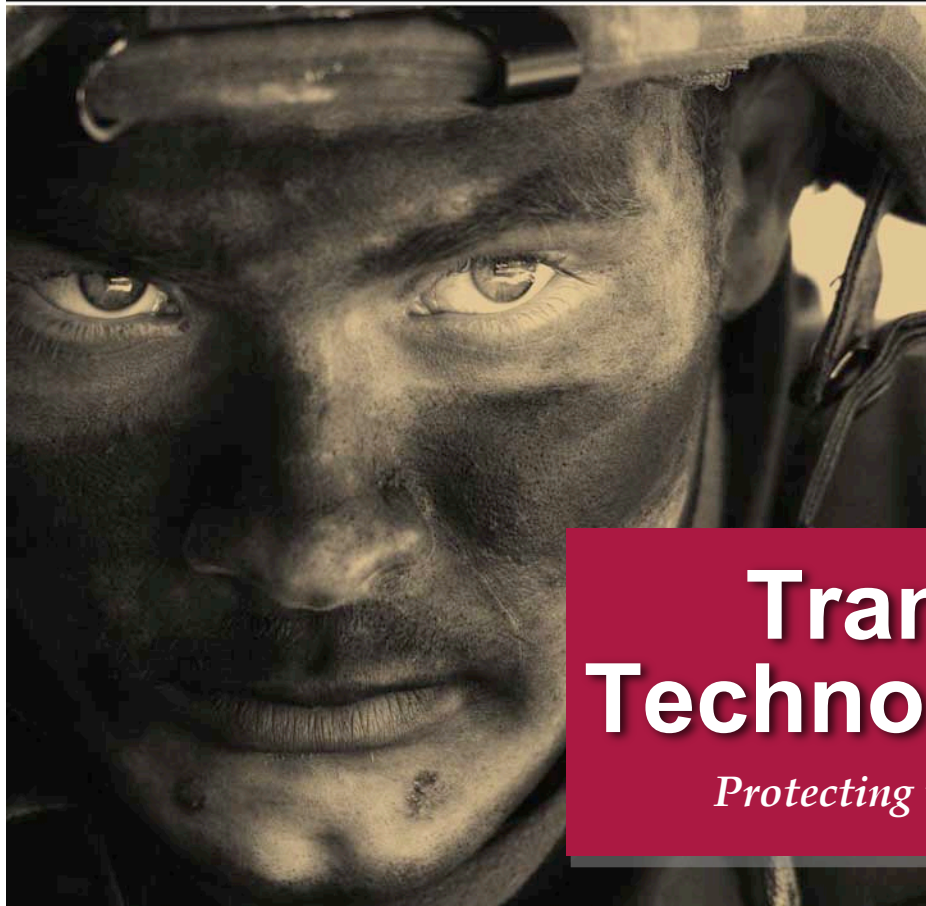


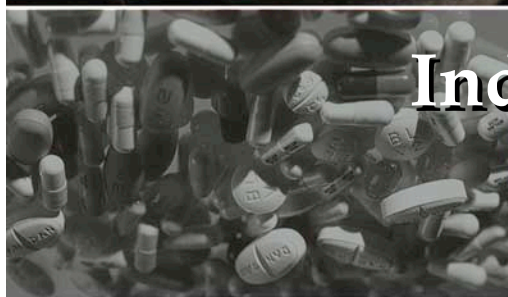
Name: Brian Reinhardt

TMTI Business Manager



# Transformational Medical Technologies Initiative (TMTI)

*Protecting the warfighter and the nation from biothreats*

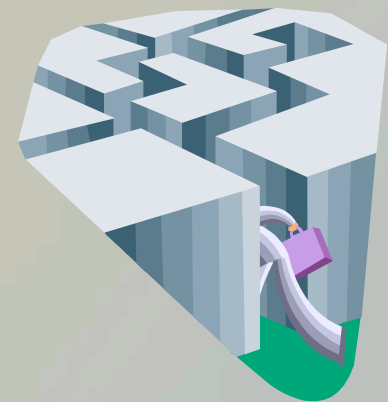


Industry Day - *"Doing Business with TMTI"*

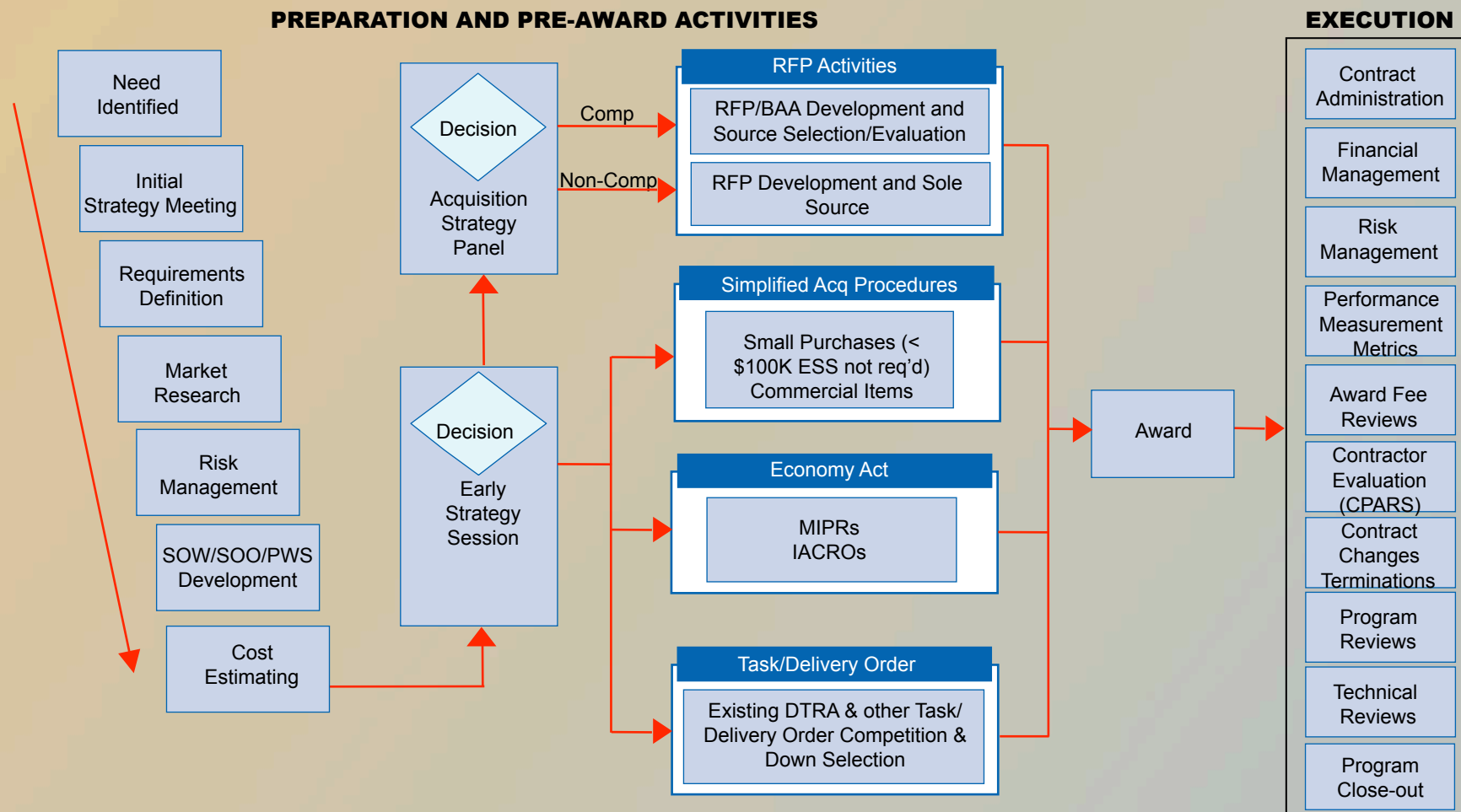
November, 2009

# Overview

- How does an idea become a product?
- Guiding Principles
- Gov't Solicitation
- Contract Negotiations
- Project Management
- Contract Closeout



## AΩ



# Overview

- How does an idea become a product?

- ***Guiding Principles***

- Gov't Solicitation
- Contract Negotiations
- Project Management
- Contract Closeout





# Guiding Principles



- **Federal Acquisition Regulation (FAR)**
  - The principal set of rules in the Federal Acquisition Regulation System
  - Title 48 of the United States Code of Federal Regulations
  - Guiding Principles
    - Satisfies customer's needs in terms of cost, quality, and timeliness
    - Minimizes administrative operating costs
    - *Conduct business with integrity, fairness, and openness*
    - Fulfill other public policy objectives
- **Defense Federal Acquisition Regulation Supplement (DFARS)**
- **DoD Directive 5000.01** - The Defense Acquisition System
- **DoD Instruction 5000.02** - Operation of the Defense Acquisition System

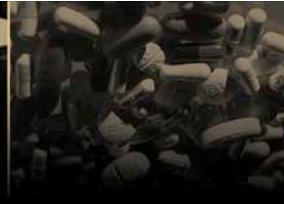
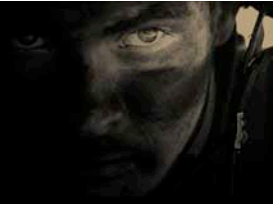


# Overview

- How does an idea become a product?
- Guiding Principles
- ***Gov't Solicitation***
- Contract Negotiations
- Project Management
- Contract Closeout



# Solicitation Types




- **RFI** - Request for Information
  - Does not result in a contract award
  - Obtain price, delivery, other market information, or capabilities for planning purposes
- **BAA** - Broad Agency Announcement
  - A *general* description of a particular DTRA R&D program that solicits participation of offerors capable of satisfying the *general* need
  - Specific criteria for Phase I and Phase II
  - Typical Criteria - Fit within program, Technically sound, Right folks
  - Excellent, Good, Fair, or Poor (“Not Selectable”)
- **RFP** - Request for Proposal
  - A formal **solicitation** resulting in a formal **contract**
  - “Solicitations under negotiated procedures are called “requests for proposals.”” (FAR 2.101)
  - Factors and significant subfactors that will be used to evaluate the proposal and their relative importance



# Broad Agency Announcement - Process



- **Solicitation** - Federal Business Opportunities ([www.fbo.gov](http://www.fbo.gov))
- **Phase I** - White Paper/Quad 
  - 1-2 Months to submit from initial announcement
  - 1 Month review to select for Phase II
- **Phase II** - Full Proposal
  - 45 days to submit
  - 2 Months for scientific review
- **Source Selection**
  - Identify awardee list - announced on FedBizOpps
  - Identify Reserve list - based on programmatic priority / availability of funds
- **Notification**
  - Announced on FedBizOpps
  - 1 month after scientific review complete
- **End-to-end process** - 7-8 Months





# Broad Agency Announcement - Evaluation Criteria

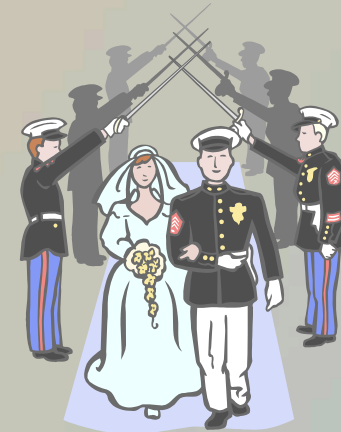


- Conducted based upon a technical subject matter expert review as described in FAR 6.102(d)(2) and 35.016
- Each proposal will be evaluated based on the merit and relevance of the specific proposal as it relates to the **topic area**\*\*\*
- **Phase I Criteria**
  - Excellent, Good, Fair, or Poor ("Not Selectable")
  - Scientific and Technical Merit
  - Value to the Joint Chemical and Biological Defense Program Goals
- **Phase II Criteria**
  - Same 3 as Phase I
  - Capability of the Personnel and Facilities to Perform the Proposed Effort
  - Cost Realism
  - Other Factors - duplication of research, program balance, past performance and budget limitations



# Overview

- How does an idea become a product?
- Guiding Principles
- Gov't Solicitation
- ***Contract Negotiations***
- Project Management
- Contract Closeout



# Contract Negotiations



- **BAA Awardee List** - FedBizOpps
- **Contracting Officer Representative (COR) Assignment**
- **Technical/Cost Reasonable Evaluation**
  - Direct/Indirect Costs
  - Materials
  - Technical Performance (including Subcontract work)
- **Fact Finding Letter (FFL)**
  - Clarify costs, equipment, subcontractors
  - Adjustment of scientific tasks
- **Resubmit Proposal** - 2 weeks from receipt of FFL
- **DCAA Audit** - Discussed in next brief



# Contract Negotiations - Con't



- **Intellectual Property - Point of negotiation (FAR 27.1-4)**
  - Declare intellectual property in proposal - BAA instructions
  - Patent Rights
  - Gov't Use Rights
- **Contract Data Requirement List (CDRL)**
  - Level 3 Work Breakdown Structure (WBS)
  - Monthly Invoicing
  - Quarterly Status/Financial Report
  - Annual Report
  - Integrated Master Schedule
  - Final Report
  - Expenditure Forecast
- **Types of contracts** - Cost Contracts (R&D)
- **Contract signing** - 4-6 months





# Overview

- How does an idea become a product?
- Guiding Principles
- Gov't Solicitation
- Contract Negotiations
- ***Project Management***
- Contract Closeout




# Program Management - Team Effort



- **COR/PM**

- Primary DoD contact
- Limitation of Authority (DFAR 252.201-9003)
- Disclosure of Information (DFAR 252.204-7000)

- **Program Metrics**

- Funding (**Cost**) 
  - Spend Plan - Provided by performer
  - Invoicing - critical to success of TMTI program
  - Incremental Funding - Limitation of funds (FAR 52.232-22)
- Milestones (**Schedule**)
  - Work Breakdown Structure
  - Gantt Chart
  - Technology Readiness Levels
- Science Reviews (**Performance**)



≥ Baseline

1-10 % Baseline

< 10 % Baseline

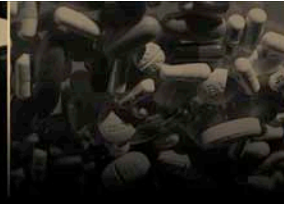
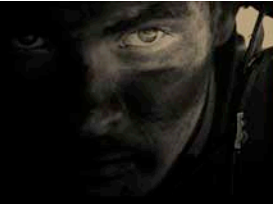
# Program Management - Team Effort (Con't)



- **Program Management Reviews**
  - Stop light for Cost, Schedule, Performance
  - Quarterly Reviews
  - Program Director Decisions
- **Contract Options** - 60 Day Notification
  - Milestone/Time Based
- **Contract Modifications** - 160 days to complete
  - Within Scope of contract
  - Cost Growth Considerations
- **Contractor Performance Assessment Reporting System (CPARS) (DFAR 252.242-9000)**
  - Provides a rating and narrative on cost, schedule, performance, and others
  - An **Initial** assessment is due 180-365 days after award
  - An **Intermediate** assessment is due annually
  - A **Final** assessment



# Overview

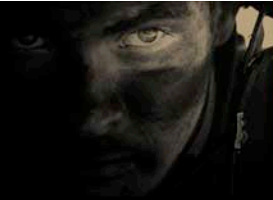


- How does an idea become a product?
- Guiding Principles
- Gov't Solicitation
- Contract Negotiations
- Project Management
- *Contract Closeout*

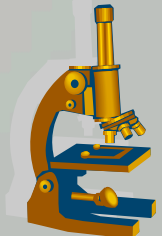




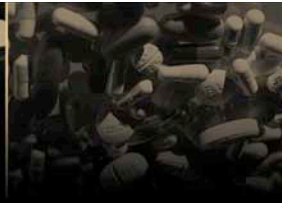
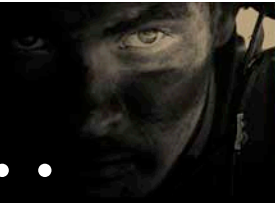
# Contract Closeout



- **Product Delivered**
  - Instructions in CDRLs
  - Gov't POC for delivery
  - Contracting Office
- **Final Invoices**
  - Last day to incur cost - end date of contract
  - Can invoice after contract ends
- **Government Property Disposition**
  - Program Office directed
  - FAR 45 (Government Property)
  - What is Gov't Property
    - Provided to the contractor by the gov't
    - Purchased using contract funds
- **Final CPARS**

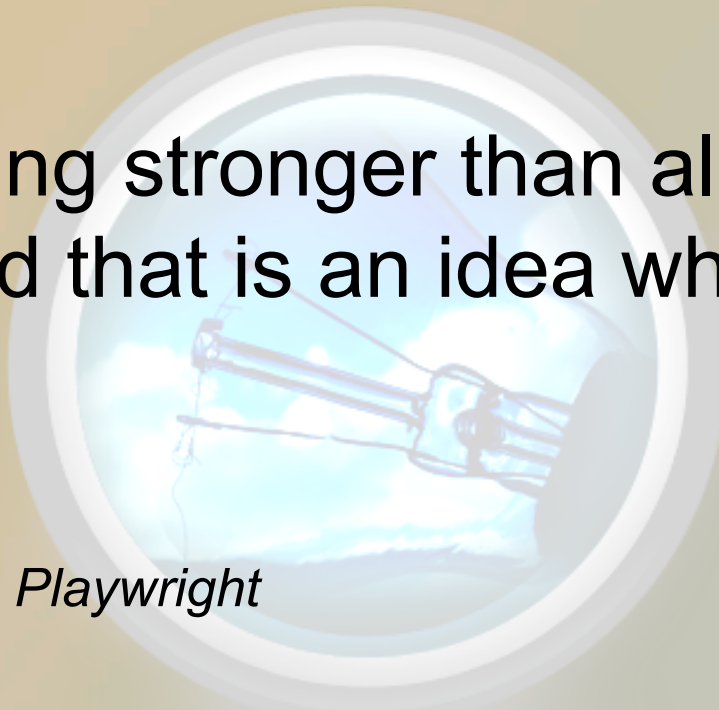


# Closing Thought . . .



There is one thing stronger than all the armies  
in the world, and that is an idea whose time  
has come.

*Victor Hugo (1802-1885) Playwright*



# Upcoming Business Opportunities



Program	Estimated Target BAA Release	Target Funding Year
<b>Transformational Medical Technology Initiative (TMTI)</b> Email: <a href="mailto:TMTIwebsite@dtra.mil">TMTIwebsite@dtra.mil</a> Website: <a href="http://www.TMTI-cbdefense.org">www.TMTI-cbdefense.org</a>	2QFY10	FY12-13
<b>DTRA "Innovation" BAA</b> FedBizOpps-HDTRA1-07-RDINO-BAA <a href="https://www.fbo.gov">https://www.fbo.gov</a>	Open BAA	Dependent on funds availability
<b>Small Business Innovation Research (SBIR)</b>	TBD	FY11
<b>CB Defense S&amp;T Program</b> <a href="https://www.fbo.gov">https://www.fbo.gov</a>	4QFY10	FY12-13
<b>TMTI - Request for Information - Counter Measure Development</b> FedBizOpps - CBM090016086	Open 29 Sep 09 Close 22 Jan 10	FY11
<b>TMTI - Request for Information - Pathway / Target ID</b> FedBizOpps - CBM090016086	Open 21 Sep 09 Close 15 Jan 10	FY11

# Upcoming Business Opportunities - con't



Program	Estimated Target BAA Release	Target Funding Year
<b>TMTI - Request for Information Clinical Data to Support Product Licensure Under the Animal Rule</b> FedBizOpps - TBD	1QFY10	FY11
<b>TMTI - Request for Information Centralized Database for Animal Model Development and Evaluation Data</b> FedBizOpps - TBD	1QFY10	FY11
<b>TMTI - Request for Information Regulation of Host Response as a Medical Countermeasure Approach</b> FedBizOpps - TBD	1QFY10	FY11



# How to Contact Us

- The TMTI website provides general information about the TMTI program, its mission, and goals – [www.tmti-cbdefense.org](http://www.tmti-cbdefense.org)
- Official government solicitations can be found at [www.fedbizops.gov](http://www.fedbizops.gov)
- E-mail us directly – [tmtiwebsite@dtra.mil](mailto:tmtiwebsite@dtra.mil)



**TRANSFORMATIONAL MEDICAL TECHNOLOGIES INITIATIVE**  
Protecting the Warfighter and the Nation from Biothreats

Links

**Home** | **About TMTI** | **Open for Business** | **News & Events** | **Resource Center**

**RDT & E**  
Read the latest news on the Medical Biodefense field's efforts to develop medical countermeasures **GO**

**RDT & E**  
Pharmaceuticals  
Biotech  
Biodefense  
DoD/Federal Agencies

**From the Press Room**

- » TMTI to Exhibit at ICAAC
- » Alnylam, Isis in Drug Collaboration
- » AVI BioPharma Files IND for Clinical Trial of Marburg Virus Treatment
- » AVI BioPharma Files IND for Clinical Trial of Ebola Virus Treatment
- » Ebola Fighter AVI Biopharma Gears Up for Biodefense Contracts

**Page Tools**  
Text size: S | M | L | XL  
» **Print** this page  
» **Share** this page  
» **Email** updates  
» **Subscribe** to feeds

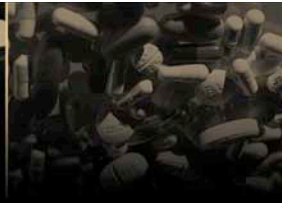
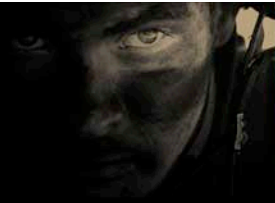
**About TMTI** | **Open for Business** | **News & Events** | **Resource Center**

<ul style="list-style-type: none"><li>» History</li><li>» Mission &amp; Vision</li><li>» Organization &amp; Oversight</li><li>» Accomplishments</li></ul>	<ul style="list-style-type: none"><li>» Solicited Proposals</li><li>» Unsolicited Proposals</li></ul>	<ul style="list-style-type: none"><li>» Press Releases<ul style="list-style-type: none"><li>· Current</li><li>· Archive</li></ul></li><li>» Events Calendar</li><li>» Contracts &amp; Awards</li></ul>	<ul style="list-style-type: none"><li>» Reports</li><li>» Key Reference</li><li>» Presentations</li><li>» Brochure</li></ul>
---	---	--	--

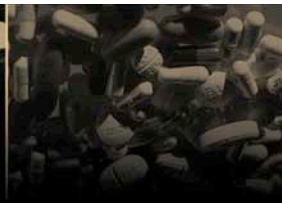
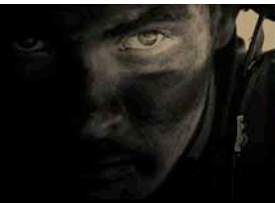
**Sitemap** • **Acronyms** • **Disclaimer** • **Contact Us**

*This site was last updated August 24, 2009.*

# Questions



# Back Up



# BAA Quad Template



**Objective:** Clear, concise (1-2 sentences) description of the goal of the effort (Arial 12 point).

**Description of Effort:** Brief description of the technology proposed for investigation and the methodologies to be used during the course of investigation (Arial 12 pt)

**Picture or graphic  
that illustrates the  
technology or concept**

**Benefits of Proposed Technology:** Brief statement that identifies the net advantage of the proposed technology over current practices and other competing technologies. (Arial 12 pt)

**Challenges:** A bullet list of the technical or scientific challenges being addressed (Arial 12 pt).

**Maturity of Technology:** Describe the maturity of the proposed technology with respect to the Technology Readiness Level (TRL) at project start and anticipated TRL at project end (Arial 12 pt).

**Research Area:** Indicate the Research Area: Reference Attachment 8 of this BAA (Arial 12 pt)

**Major Goals/Milestones by fiscal year:**

- Bullet list (Arial 12 pt)

**Proposed Funding (\$K): Total \$K (Arial 12 pt)**

Year 1 Funding: \$K

Year 2 Funding: \$K

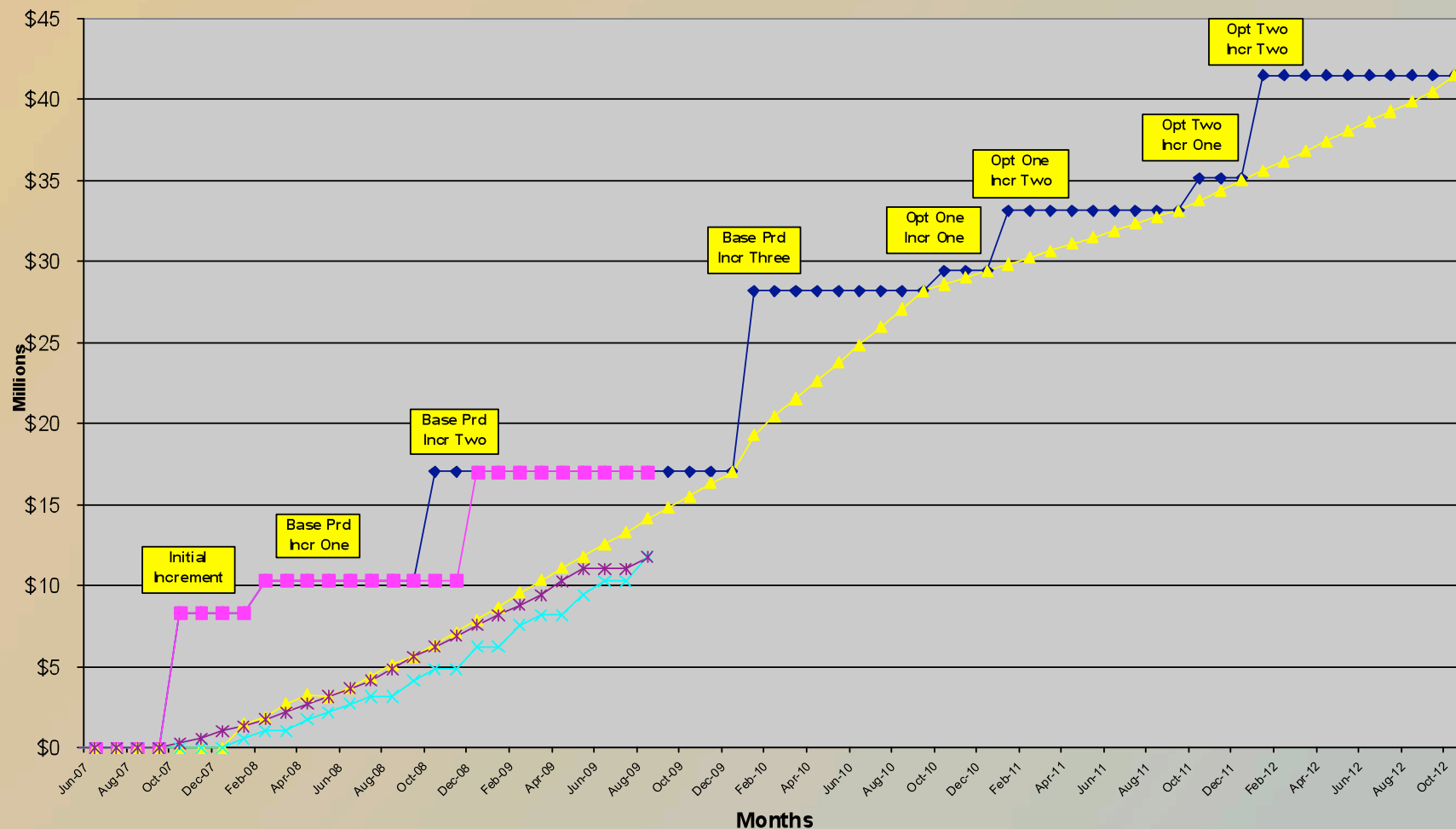
etc

**Period of Performance: (months) (Arial 12 pt)**

**PI contact info:** e.g. Dr. Marge N. Overra, (123) 123-1234  
Marge.N.Overra@innovationsrus.com (Arial 12 pt)



# Snake Chart Template



◆ Obligation Forecast
■ Obligation Actual
▲ Expenditure Forecast
✕ Expenditure Actual (CCaRS)
\* Accrual Actual